



INVESTOR IN PEOPLE

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Your Reference: PAC
Application No: GB 0022570.6

28 February 2001

Dear Sirs

**Patents Act 1977:
Combined Search and Examination Report under Sections 17 and 18(3)**

Latest date for reply: 17 September 2001

I enclose two copies of my search and examination report and two copies of the citations.

By the above date you should either file amendments to meet the objections in the report or make observations on them. If you do not, the application may be refused.

Publication

I estimate that, provided you have met all formal requirements, preparations for publication of your application will be completed soon after **3 April 2001**. You will then receive a letter informing you of completion and telling you the publication number and date of publication.

Amendment/withdrawal

If you wish to file amended claims for inclusion with the published application, or to withdraw the application to prevent publication, you must do so before the preparations for publication are completed. **No reminder will be issued.** If you write to the Office less than 3 weeks before the above completion date, please mark your letter prominently: **"URGENT - PUBLICATION IMMINENT".**

[†]**Use of E-mail:** Please note that e-mail should be used for correspondence only.



Yours faithfully

Rowena Dinham.

Dr Rowena Dinham
Examiner

Important information about combined search and examination

I also ask that you take note of the following points. These might have a bearing on the future stages of your application because the examination report has been sent to you before your application has been published.

- (a) You may file voluntary amendments before making a full response to my examination report. We will publish with your application any new or amended claims you file voluntarily or as a full response, provided that they are received before preparations for publication are completed. It would help us when you file amendments before publication if you could prominently indicate in a covering letter whether or not the amendments are intended as a full response to the examination report.
- (b) If you file a full response to the examination report before your application is published I will consider it as soon as possible. However, if this would disrupt the publication of your application, I would have to delay taking any action until the application had been published. This delay could be up to 3 months, depending upon when we receive your response.
- (c) There is another situation when there might be a delay between you filing a full response and the Patent Office responding to it. This would arise if you met all my objections but your application had not or had only recently been published. I could not report the outcome of my re-examination until I was satisfied that the search was complete for documents published before the priority date of your invention and that anybody interested in the application has had three months following publication of the application to make observations on the patentability of your invention.
- (d) Provided that the requirements of the Act have been met, I can send your application to grant as early as three months after publication. Before doing so I will bring the original search up to date and raise with you any further objection that might result from this top-up search. However, there is a possibility that at that time I may not have access to all the patent applications published after the priority date of your invention and of possible relevance to your application. If this is the case I would have to complete the search after grant and if necessary raise any new found novelty objection then.



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Application No: GB 0022570.6
Claims searched: All

Examiner: Dr Rowena Dinham
Date of search: 26 February 2001

Patents Act 1977

Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.S):

Int Cl (Ed.7):

Other: ONLINE: WPI, JAPIO, EPODOC, TXTE, EMBASE, MEDLILNE, CAPLUS, BIOSIS, SCISEARCH

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
A	WO99/10488A (THE SALK INSTITUTE FOR BIOLOGICAL STUDIES) See especially page 7 line 1-13 and examples	
A	<i>J Biochem</i> ; Vol 127 (3), pp 367-372 (2000). Koresawa <i>et al.</i> See entire document.	
A	<i>J Biol Chem</i> ; Vol 274 (53) , pp 37923-37931 (1999). Forlino <i>et al.</i> See especially Results and Discussion	
A	<i>Methods (Orlando)</i> ; Vol 14 (4), pp 381-392 (1998). Sauer. See entire document	
A	<i>Proc Natl Acad Sci USA</i> ; Vol 85 (14), pp 5166-5170 (1988). Sauer and Henderson. See especially Results and Discussion	

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.



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Application No: GB 0022570.6
Applicant: President of Osaka University
Latest date for reply: 17 September 2001

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Patents Act 1977

Combined Search and Examination Report under Sections 17 & 18(3)

Section 4(2)

1. Claim 12 defines a method of knocking in a gene, which can be regarded as a method of gene therapy, and as such is regarded as a method of treatment, which is therefore not patentable according to section 4(2). This claim should therefore be restricted to an *in vitro* method. Likewise, claim 13 should also be restricted to an *in vitro* method. The description will also require amendment in this respect.

2. Claim 21 relates to a method of treatment of the human or animal body and is therefore not patentable according to section 4(2). This claim should therefore be deleted or suitably amended. The description will also require amendment in this respect

Section 1(3)(a)

3. The 'animal' of claims 8, 15 and 16 should be restricted to a non-human animal. Likewise, the 'organ' of claim 9 should also be restricted to a non-human organ. Additionally, the 'tissue' and 'cell' of claims 10 and 11 respectively should either be restricted to non-human tissue or cell, or alternatively a human tissue or cell may be claimed when *in vitro*. The description will also require amendment in this respect.

Consistency

4. The use of the term 'animal' in claim 8 is inconsistent with the invention as defined in claim 1 which states that the gene is for use in mammals, and furthermore, this term would appear to be unsupported by the description which demonstrates the expression of the gene in mammalian cells only.

Support by the description

5. The reference on page 4 lines 13 and 16, and page 7 line 21 to 'sequence number 1' is confusing since it suggests to the reader that the actual nucleotide sequences are disclosed, yet there are no sequence listings in the document. Likewise, the reference on page 4 line 20 to 'sequence number 2' is also confusing.

6. The passage on page 23 line 3-15 obscures the scope of the claims and should therefore be deleted.



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[Examination Report contd.]

Description

7. You should note that sections of the description have been poorly translated, for example the term 'recombinize' on page 1 line 15 should apparently read 'recombine'. You may wish to consider filing a more efficiently translated version of the description when making your amendments.